K102996

p1of2

# Medivators Advantage Plus Endoscope Reprocessing System

510(k) Summary of Safety and Effectiveness
Prepared December 27, 2010

JAN 13 2011

510(k) Number: K102996


Manufacturer: Medivators Reprocessing Systems, a Division of Minntech Corporation

Address: 14605 28th Avenue North
Mpls., MN 55447
USA

Official Contact: Lynn Lueders
Director, Regulatory Affairs
(763) 553-3300


Device Name:

Trade or proprietary name: Medivators Advantage Plus Endoscope Reprocessing System

Common or usual name: Endoscope washer/disinfector

Medivators has supplied the following information to the U.S. Food and Drug Administration to support the substantial equivalence of a cleaning claim for the Advantage Endoscope Reprocessing System to other endoscope reprocessors currently marketed in the U.S.

## 1. Device Description

The Advantage AER is an electro-mechanical system intended to test, clean, and high level disinfect fiberoptic and video endoscopes and their related accessories between uses.

The Advantage system uses the peracetic acid based Rapicide PA High Level Disinfectant.

The AER machine has the capability of cleaning endoscopes as part of the overall cleaning/disinfection cycle of the machine. The users may use the cleaning cycle to replace manual cleaning of the endoscope, however, the users are instructed that they need to preclean the endoscope immediately after use to the SGNA and facility guidelines.

## 2. Intended Use

Medivators Advantage Plus Endoscope Reprocessing System tests, cleans, disinfects and rinses endoscopes, such as fiberoptic and video endoscopes between patient uses. The Advantage Plus system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes and related accessories. Manual cleaning of endoscopes is not required prior to placement in the Advantage Plus system. The scopes must be precleaned immediately after use.

The Advantage Plus Endoscope Reprocessing System uses Rapicide PA High Level Disinfectant to provide high level disinfection of endoscopes when used according to the directions for use. The system uses Intercept Detergent in its cleaning cycle at a concentration of 0.5%.

Rapicide PA Test Strips are used after the disinfection cycle to ensure that the used disinfectant is above the minimum recommended concentration (MRC) of 850ppm peracetic acid; this ensures that the disinfectant was above MRC during the entire disinfection cycle. Rapicide PA should be used in the Advantage Plus System under the following contact conditions:

| | |
|---|---|
| Contact Time: | 5 minutes |
| Temperature: | 30°C |
| MRC: | 850ppm |

**3. Comparison to Another Device in Commercial Distribution Within the United States**

The Advantage Plus with a cleaning claim is the same machine as the original Advantage Plus AER. The machine function has not been changed. It has been shown to be equivalent to the Advanced Sterilization Products' EvoTech™ Integrated Endoscope Disinfection System (K061899). The machines have the same indications for use and the same methods of providing disinfection. The ASP EvoTech system and the Advantage system cleans the endoscopes, allowing the placement of the endoscopes into the machine without manual cleaning.

**4. Summary of Testing**

Medivators has provided testing to show that the Advantage Endoscope Reprocessing system cleaning cycle is safe and effective for its intended use.

Testing was presented to show that the cleaning cycle is efficacious and allows users to place used endoscopes into the machine without prior manual cleaning (users do need to preclean the scopes immediately following use).

This testing included simulated use testing with the major brands of endoscopes and testing of used clinical scopes. Testing also included the evaluation of our soil recovery procedures.

**5. Summary of Substantial Equivalence**

Medivators has provided the above information in the form of a 510(k) to support the claim that the Advantage Endoscope Reprocessing System will clean endoscopes in order to eliminate manual cleaning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Lueders
Director, Regulatory Affairs
Medivators Reprocessing Systems
14605 28th Avenue North
Minneapolis, Minnesota 55447

JAN 13 2011

Re: K102996
Trade/Device Name: Medivators Advantage Plus Endoscope Reprocessing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: December 28, 2010
Received: December 29, 2010

Dear Ms. Lueders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

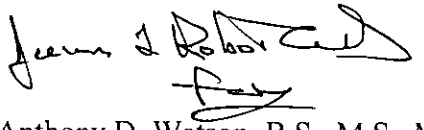
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

JAN 13 2011

510(k) Number (if Known): K 102996

Device Name: Medivators Advantage Plus Endoscope Reprocessing System

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Prescription Use ____ AND/OR Over-the Counter Use _X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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